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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/815,707	04/02/2004	Alan K. Smith	250512US	9727

22850 7590 03/24/2005

OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.  
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EXAMINER

BELYAVSKYI, MICHAEL A

ART UNIT PAPER NUMBER

1644

DATE MAILED: 03/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/815,707

**Applicant(s)**

SMITH ET AL.

**Examiner**

Michail A. Belyavskyi

**Art Unit**

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 46-77 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 46-77 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

1. Applicant's amendment, filed 04/02/04 is acknowledged.

Claims 46-77 are pending.

In view of Applicant's Amendment filed on 04/02/04 that was not timely entered, the previous Restriction Requirement mailed on 09/27/04 is hereby vacated. The new Restriction Requirement is set forth below. Examiner apologized for any inconveniences.

### *Restriction Requirement*

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:
  - I. Claims 51 and 59 drawn to a composition comprising lineage committed dendritic cells, wherein said cells are **antigen primed dendritic cells**, classified in Class 435, subclass 325.
  - II. Claims 52 and 60 drawn to a composition comprising lineage committed dendritic cells, wherein said cells are **myeloid derived dendritic cells**, classified in Class 435, subclass 325.
  - III. Claims 53-61 drawn to a composition comprising lineage committed dendritic cells, wherein said cells are **non-myeloid derived dendritic cells**, classified in Class 435, subclass 325.
  - IV. Claims 67 and 75 drawn to a method for treating a human patient in need of an infusion of lineage committed dendritic cells comprising administering a composition of lineage committed dendritic cells, wherein said cells are **antigen primed dendritic cells** classified in Class 424, subclass 93.1.
  - V. Claims 68 and 76 drawn to a method for treating a human patient in need of an infusion of lineage committed dendritic cells comprising administering a composition of lineage committed dendritic cells, wherein said cells are **myeloid derived dendritic cells** classified in Class 424, subclass 93.1.

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VI. Claims 69 and 77 drawn to a method for treating a human patient in need of an infusion of lineage committed dendritic cells comprising administering a composition of lineage committed dendritic cells, wherein said cells are **non-myeloid derived dendritic cells** classified in Class 424, subclass 93.1.

3. Claims 46-50 and 54-58 link inventions of Groups I-III and Claims 62-66 and 70-74 link inventions of Groups IV-VI. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 46-50 and 54-58 or 62-66 and 70-74. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

4. Groups I - III are different products. Antigen primed dendritic cells, myeloid derived dendritic cells and non-myeloid derived dendritic cells differ with respect to their structures physicochemical properties and mode of action which require non-coextensive searches; therefore each product is patentably distinct

5. Groups IV- VI are different methods. These inventions are different with respect to ingredients, method steps, and endpoints which require non-coextensive searches ; therefore, each method is patentably distinct.

6. Groups I-III and IV-VI are related as product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the lineage committed cells can be used to produced conditioning media in addition to the methods of treating .

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7. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Moreover, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention. Therefore restriction for examination purposes as indicated is proper.

8. The examiner has required restriction between product and process claims. If applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

9. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

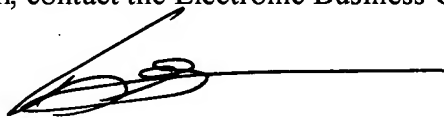
A telephone call was made to Daniel Perreira on 3/11/05 to request an oral election to the above restriction requirement, but did not result in an election being made.

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10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskyi whose telephone number is 571/ 272-0840. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571/ 272-0841.

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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March 18, 2005